DEC 1 2 2000

510(K) SUMMARY

OPUS 20 DENTAL LASER SYSTEM

510(k) Number K002899

Applicant's Name:

OpusDent Ltd.
Atidim Science Based industrial Park, Neve Sharett
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Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
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Or:

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as Regulatory Counsel.
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555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
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Date Prepared:

September 2000

Trade Name:

Opus 20 Dental Laser System

Classification Name:

Laser Instrument, Surgical, powered

Classification:

FDA has classified laser surgical instrument for use in general and plastic surgery (product code GEX) as a class II device. This type of product is reviewed by the General & Plastic Surgery Panel.

Predicate Device:

The Opus 20 Dental Laser System is comprised of Er:YAG laser component and a CO_2 laser component.
The Opus 20's Er:YAG component is substantially equivalent to the Del2940 Dental Erbium Laser, DeLite Dental Erbium (Continuum Biomedical, Inc.) cleared under K992013 in terms of intended use, indication for use, performance, technological characteristics and user interface.
The Opus 20's CO_2 component is substantially equivalent to the Sharplan Model 1015 CO_2 Laser (ESC Medical Systems, Inc.) cleared under K950725 and K971743 in terms of intended use, indication for use, performance, technological characteristics and user interface.
The general system structure is substantially equivalent to the Derma K ER:YAG/CO_2 Laser (ESC Medical Systems, Inc.) cleared under K982827.

Performance Standards:

The Opus 20 Dental Laser complies with:
U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.
In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards, EN 60601-1, EN-60825-1, EN-601-2-22, CISPR 11, IEC 61000-4-2/3/4/5, EN55011 and IEC 801-2
In compliance with these standards, Opus 20 is equipped with:
interlock protective housing, laser emission indicators, beam shutters, energy and power display, master key switch, emergency shut-off knob, remote interlock connector and proper labeling.

Intended Use / Indication for Use:

The Opus 20 Dental Laser System is intended to aid during dental procedures performed either in hard or soft oral tissue.
The Er:YAG laser component is indicated for caries removal, cavity preparation, and enamel etching.
The CO_2 laser component is indicated for vaporization, incision, excision and coagulation of oral soft tissue in procedures such as gingivectomy; frenum release; removal of soft tissue, cysts and tumors.

Device Description:

Opus 20 is a dual laser system incorporating an Er:YAG laser and a CO_2 laser. The system is operating at a wavelength of 2.94 microns and 10.6 microns respectively. The Er:YAG laser delivers to the tissue pulses with energies up to 1 joule per pulse and power up to 12 Watts. The CO_2 laser delivers to the tissue up to 10 Watts.

Substantial Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The Opus 20 intended use and indications for use were previously cleared by FDA for the predicate devices.

- The technical characteristics of the Er:YAG laser of the Opus 20 system are similar to those of the DeLite predicate device. Both devices have the same theory of operation and laser medium. Both devices have the ability to deliver the same wavelength at a similar average power and pulse rate. The technical characteristics of the CO_2 laser of the Opus 20 system are similar to the 15F predicate device. Both devices have the same theory of operation and laser medium. Both devices have the ability to deliver the same wavelength at the same maximal power pulse rate and pulse duration.

- Laser output values of the Opus 20 are well within previous cleared values of the predicate devices as described.

- The predicate devices and other previous cleared lasers with similar energy output has a proven safety and effectiveness in the treatment of the claimed indications.

- Safety and performance testing.

Therefore, we believe that the Opus 20 Dental Laser System is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2000

OpusDent, Ltd.
c/o Ms. Shoshana Friedman, RAC
Push-Med Ltd.
117 Ahuzah Street
Ra'ananna 43373, Israel

Re: K002899
Trade Name: Opus 20 Dental Laser
Regulatory Class: II
Product Code: GEX
Dated: September 13, 2000
Received: September 18, 2000

Dear Ms. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K002899

Device Name: Opus 20 Dental Laser System

Indications for Use: The Opus 20 Dental Laser System is intended to aid during dental procedures performed either in hard or soft oral tissue.

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number K002899

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N. Melkerson
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002899